The Tobacco Settlement: An Overview

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SUMMARY

On June 20, a group of state attorneys general, plaintiffs' lawyers, public health advocates, and lawyers representing cigarette manufacturers announced an historic settlement that would restructure the tobacco industry and revolutionize the nation's tobacco control efforts. The proposed settlement is currently under congressional consideration, and would require legislation and the President's approval before taking effect.

The agreement would settle lawsuits brought by 40 states seeking to recoup Medicaid spending for smoking-related illnesses and ban class-action lawsuits against the tobacco industry. The industry, in turn, would pay an estimated $386.5 billion over the next 25 years to compensate states and individuals for tobacco-related health costs and finance nationwide anti-smoking programs. The settlement also purports to incorporate and expand upon the recent Food and Drug Administration's (FDA) regulation of tobacco products. The sale of tobacco products to adults would remain legal, but subject to restrictive measures designed to reduce significantly sales to underage buyers.

Public health officials have raised questions about the proposed settlement concerning its potential effect on FDA's authority to regulation nicotine.

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BACKGROUND

On June 20, a group of state attorneys general, plaintiffs' lawyers, public health advocates, and lawyers representing cigarette manufacturers announced an historic settlement that would restructure the tobacco industry and revolutionize the nation's tobacco control efforts. The proposed settlement is intended to be a blueprint for congressional legislation. Two Senate committees have already held hearings on the settlement, and more are planned after the August recess as lawmakers consider how best to approach this issue.

Overview of Settlement

- Seeks to prevent underage access to, and dramatically reduce underage use of, tobacco products.

- Confirms the FDA's authority to regulate tobacco products.

- Incorporates most of the provisions of FDA's tobacco regulation, expanding them to include a ban on all outdoor tobacco advertising.

- Sets national requirements limiting smoking in public buildings and leaves states and local governments free to set more stringent requirements.

- Requires that the participating tobacco companies pay $15 billion a year to fund anti-smoking and smoking cessation programs, smoking-related health care costs incurred by federal, state and local governments, and federal and state enforcement of the proposed regulations.

- Protects the industry from all class-action lawsuits, while preserving the rights of individuals to sue the tobacco industry.

- Ensures that non-participating tobacco companies are held fully liable for any injuries their products may cause.

- Mandates changes in the corporate culture of tobacco companies in order to ensure that they comply with the spirit, as well as the letter, of the proposed resolution.

FDA's Tobacco Regulation

On August 28, 1996, the FDA issued a final regulation governing access to and advertising and promotion of nicotine-containing cigarettes and smokeless tobacco products to children and adolescents, after a 2½-year investigation of the tobacco industry and its products.[1] The agency's assertion of jurisdiction over tobacco products under the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 301) was based on the finding that cigarettes and smokeless tobacco products are delivery devices for nicotine, an addictive drug. The aim of the regulation is to reduce youth access to tobacco products and the appeal of tobacco advertising to youngsters.

The FDA regulation prohibits the sale of cigarettes and smokeless tobacco to persons under the age of 18; requires manufacturers, distributors, and retailers to comply with certain conditions regarding the sale and distribution of these products; requires retailers to verify the purchaser's age by photo identification; prohibits all free samples; prohibits vending machines and self-service displays except in adult-only facilities; limits the advertising to which children are exposed to a black-and-white, text-only format; prohibits the sale or distribution of tobacco-related promotional non-tobacco items such as hats and tee shirts; prohibits brand-name sponsorship of sporting and other events; and requires manufacturers to provide intended use information on package labels and in advertising.

On April 25, 1997, a federal district court judge in Greensboro, North Carolina ruled that the FDA has jurisdiction under the FFDCA to regulate nicotine-containing tobacco products.[2] The court held that "tobacco products fit within the FFDCA's definitions of drug and device'" and that the FDA can regulate cigarettes and smokeless tobacco products as drug delivery devices under the combination product and restricted device provisions of the Act.

However, while the court upheld all the regulation's provisions that restrict youth access and labeling, it found that the FDA lacks authority under the FFDCA to restrict the advertising and promotion of tobacco products. The court also ordered the FDA not to implement any of the provisions of the regulation that have not yet gone into effect pending further action by the court. Two access provisions—the prohibition of sales to minors under age 18 and the requirement that retailers check photo identification of customers under age 27—went into effect on February 28. All but one of the remaining provisions were scheduled to go into effect on August 28, 1997. The federal government has appealed the advertising portion of the ruling to the U.S. Fourth Circuit Court of Appeals in Richmond, which is expected to hear the case next month.

The North Carolina decision gives the FDA broad authority to regulate nicotine-containing tobacco products, including the authority to reduce or even eliminate nicotine and other ingredients in cigarettes and smokeless tobacco. The proposed tobacco

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[1] Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. *Federal Register,* v. 61, no. 168, Aug. 28, 1996. p. 44396-45318.

[2] Coyne Beahm, Inc. v. Food and Drug Administration, 958 F. Supp 1060 (M.D.N.C. Apr. 25, 1997).

settlement would explicitly recognize the agency's authority to regulate tobacco products and codify that authority in law.

However, public health officials have criticized the settlement on the grounds that it places undue restrictions on FDA's authority to regulate nicotine. For example, under the settlement any proposal to reduce the level of nicotine in cigarettes would require a formal rule making and be subject to congressional review. The agency would also have to demonstrate that the proposed reduction in nicotine significantly reduces health risks and does not create a black market for unmodified products. In addition, the FDA would be required to wait 12 years before proposing to eliminate nicotine from tobacco products.

Table 1, which begins on the following page, provides a detailed outline of the provisions of the settlement.[3] The citations in parentheses in Title I of the settlement refer to section 897 of the FDA regulation. The provisions of that regulation, including the dates on which they become effective, are listed in Table 2.

[3] The information in Table 1 is drawn from the 68-page settlement document, which is entitled Proposed Resolution and dated June 20, 1997. The document was obtained from representatives of parties involved in the tobacco settlement negotiations.

TABLE 1: PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
I. Reformation of the Tobacco Industry	
A. Marketing and Advertising	Incorporates the following provisions of the FDA rule: (i) Prohibits use of non-tobacco brand names for tobacco products unless such names were in existence as of 1/1/95 (897.16(a)); (ii) Restricts tobacco product advertising to FDA-specified media (897.30(a)); (iii) Restricts permissible tobacco product advertising in adult-only facilities and adult publications to black text on a white background (897.32 (a-b)); (iv) Requires advertisements to include FDA-mandated statement, "Nicotine-Delivery Device for Persons 18 and Older" (897.32(c)); (v) Bans sale and distribution of non-tobacco items, services, and gifts, and brand-name sponsorship of sporting and other cultural events (897.34(a-c)). Modifies and extends the FDA rule as follows: (i) Bans **all** outdoor tobacco product advertising (modifies 897.30(a-b)); (ii) Bans the use of human and cartoon images in tobacco advertising and packaging; (iii) Prohibits tobacco product advertising on the Internet unless designed to be inaccessible from the United States; (iv) Prohibits payments to glamorize tobacco use in media appealing to minors; (v) Prohibits payments for tobacco product placement in movies, TV programs, and video games; (vi) Establishes additional restrictions on point-of-sale advertising.
B. Warnings, Labeling and Packaging	Amends the Federal Cigarette Labeling and Advertising Act (15 U.S.C. 1331 *et seq.*) and the Comprehensive Smokeless Tobacco Health Education Act (15 U.S.C. 4401 *et seq.*) to require new warning labels on tobacco product packages and cartons, and on all tobacco advertisements. For cigarettes, the warnings would be in bold type and occupy 25% of the front of the package.[a] Requires packages to include FDA-mandated statement, "Nicotine-Delivery Device for Persons 18 and Older" (897.25). Transfers from the Federal Trade Commission (FTC) to FDA the authority to measure and report tar, nicotine, and carbon monoxide levels in tobacco smoke, and the authority to require disclosure of such information on labels and advertising.
C. Restrictions on Access to Tobacco Products	Incorporates the following provisions of the FDA rule: (i) Sets a minimum age of 18 to purchase tobacco products and requires retailers to check photo ID of anyone under age 27 (897.14(a-b)); (ii) Requires face-to-face transactions for all tobacco sales, bans sale of individual cigarettes, and requires retailers to remove all displays and advertising that do not comply with this regulation (897.14(c-e)); (iii) Establishes a minimum package size of 20 cigarettes and bans the sampling of tobacco products (897.16(b)(d)); (iv) Bans self-service displays except in adult-only facilities (897.16(c)). Modifies and extends the FDA rule by banning **all** vending machine sales and prohibiting mail-order sales except those subject to proof of age (modifies 897.16(c)). After two years, an FDA review would determine if minors are obtaining tobacco products through the mail.
D. Licensing of Retail Sales	Mandates minimum federal standards for licensing retailers who sell tobacco products. Retailers would face fines for selling tobacco without a license of at least $1,000 per violation. Licensed retailers who sell to minors would face fines starting at $500 and rising to $25,000 for repeated violations. Retailers caught selling to minors 10 times within any two-year period could lose their license. Licensing fees would cover the administrative costs of issuing state licenses.

TABLE 1: PROPOSED TOBACCO SETTLEMENT (June 20, 1997)

Title	Provisions
E. Tobacco Product Development and Manufacturing	Recognizes explicitly FDA's authority to regulate tobacco products. Classifies tobacco products as Class II devices[b] under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c) and permits FDA to require the modification of tobacco products in accordance with Performance Standards: (i) For at least 12 years following enactment of the settlement, FDA would be permitted to adopt Performance Standards to reduce nicotine yields and eliminate other harmful tobacco product ingredients, provided that the modification significantly reduces health risks, is technologically feasible, and does not create a black market for unmodified products. FDA must show "substantial evidence" for any such modification in a formal rule making subject to the Administrative Procedure Act, with the right of judicial review.[c] Any such action would also be subject to congressional review under the Regulatory Reform Act of 1996.[d] (ii) After the initial 12-year period, FDA would be permitted to adopt Performance Standards to eliminate nicotine, provided that the modification meets the same criteria listed in item (i). FDA must base any such modification on a "preponderance of evidence" pursuant to a Part 12 hearing, or notice and comment rule making, with the right of judicial review.[e] Any such action would be phased in after a two-year period to allow for congressional review under the Regulatory Reform Act of 1996. (iii) Requires FDA approval of all health claims for tobacco products. Permits FDA to mandate the introduction of less hazardous tobacco products that are technologically feasible.[f] Any such action would require a formal rule making subject to the Administrative Procedure Act, with the right of judicial review. Requires FDA to establish a scientific advisory committee to study issues related to the regulation of nicotine and other health and safety issues.
Good Manufacturing Practice	Subjects tobacco companies to good manufacturing practice standards comparable to those applicable to other FDA-regulated industries (see 820.1(e)(f)).
Industry Documents	Establishes a public depository of industry documents related to smoking and health, addiction or nicotine dependency, safer or less hazardous cigarettes, and underage tobacco use and marketing. The depository would not include documents that are determined by the industry to be "privileged against disclosure," but would instead include a detailed, descriptive log of such privileged documents. Establishes a three-judge federal arbitration panel to settle disputes over making privileged documents public.

TABLE 1: PROPOSED TOBACCO SETTLEMENT (June 20, 1997)	
Title	**Provisions**
F. Non-Tobacco Ingredients	Supersedes the current federal ingredient law by requiring manufacturers to disclose to FDA on a "strictly confidential" basis the amounts of all non-tobacco ingredients added to each brand.[g] Requires manufacturers to disclose ingredients information to the public in a manner comparable to current federal requirements for food products. Manufacturers must submit safety testing results for each non-tobacco ingredient within five years, and demonstrate that there is a reasonable certainty that the ingredient is not harmful under the intended conditions of use. FDA would have 90 days to review each safety assessment.
G. Corporate Culture and Compliance	Includes requirements to ensure that the industry complies with both the letter and spirit of the settlement, including the establishment of internal procedures to promote compliance with laws barring tobacco sales to minors. Provides "whistleblowers" in the tobacco industry with protection. Requires tobacco lobbyists to agree in writing to comply with all the provisions of the settlement, and not support or oppose any state or federal legislation without the manufacturer's authorization. Disbands the Tobacco Institute and the Council for Tobacco Research.[h]
II. Look-Back Provisions, State Enforcement Incentives	Sets targets for reduction in underage tobacco use. The industry would face fines of up to $2 billion per year if underage tobacco use does not decline by 30% in five years, 50% in seven years, and 60% in 10 years. Allows the industry to petition FDA to recover 75% of the fine if it can establish that it pursued all "reasonably available measures" to reduce youth smoking and did nothing to undermine the settlement goals. Requires states to undertake significant enforcement steps to reduce the incidence of underage tobacco use, which go beyond the provisions of the Synar Amendment (42 U.S.C. 300x-26; 45 C.F.R. 96.130). States must maintain a specific level of enforcement activity or risk losing health care funds (see Title VII).[i]
III. Penalties, Consent Decrees, Non-Participating Tobacco Companies	Violations of the proposed settlement's requirements would carry civil and criminal penalties based upon the penalty provisions of the Food, Drug and Cosmetic Act and the provisions of the United States criminal code. In addition, the industry would face civil penalties of up to $10 million for each violation of the requirements to disclose information about non-tobacco ingredients and the health effects of tobacco products. Non-participating tobacco companies would be subject to all the regulations outlined in Title I of the settlement, but would receive none of the civil liability protection outlined in Title VIII. Requires non-participating companies to make annual payments into an escrow fund earmarked for potential liability claims against the companies.
IV. Environmental Tobacco Smoke	Restricts smoking in public facilities (i.e., any building entered by 10 or more individuals at least one day a week) to separately ventilated locations. Ensures that no employee may be required involuntarily to enter a smoking area. Exempts restaurants (other than fast food restaurants) and bars, private clubs, hotel guest rooms, casinos, bingo parlors, tobacco merchants and prisons.[j] Allows state and local governments to enact stricter laws.

TABLE 1: PROPOSED TOBACCO SETTLEMENT (June 20, 1997)	
Title	**Provisions**
V. Scope and Effect	The settlement includes all tobacco products sold in U.S. commerce, and also covers imports and U.S. duty free items. Preserves the legal authority of state and local governments to regulate further the sale and distribution of tobacco products. Retains the fiscal authority over tobacco products of the Bureau of Alcohol, Tobacco and Firearms, and the existing authority of the FTC, except for tar, nicotine and carbon monoxide testing (see Title I, sec. B).
VI. Programs and Funding	Mandates annual industry payments in perpetuity to reimburse states for Medicaid outlays for smoking-related illnesses,[k] pay damages to settle individual lawsuits (see Title VIII), provide funds for public health programs, and to cover the costs of implementing and enforcing the programs and regulations outlined in the settlement (see Title VII). The industry would pay an up-front sum of $10 billion, and annual payments beginning at $8.5 billion in the first year, increasing to $15 billion in the fifth year of the settlement. The annual payments would remain at $15 billion per year thereafter. The annual payments would be subject to adjustment for inflation, and would be deemed an ordinary and necessary business expense and, therefore, tax deductible. Companies would raise prices on tobacco products to cover the cost of the annual payments.[l] If adult cigarette sales dropped below 1996 levels, the companies would get a rebate on their annual payments. **Total estimated payments over the first 25 years = $368.5 billion (in 1997 dollars)[m]**
VII. Public Health Funds	Recommends allocating a portion of the annual payments to fund a variety of public health programs and activities to discourage tobacco use among youngsters and encourage current tobacco users to quit. Financial assistance would be provided to smokers trying to quit. Funds would also be used to compensate sporting and cultural events and entities that lose their tobacco industry sponsorship (see Title I). Finally, public health funds would be used by FDA to implement and enforce its regulations (see Title I), and to enforce the state-administered retail licensing requirements (see Title I) and the Synar Amendment (see Title II).
VIII. Civil Liability	Provides the participating companies with protection from civil liability by legislatively settling the state attorneys generals' and class-action lawsuits. Prohibits future class-action lawsuits. Preserves the rights of individuals to sue tobacco companies for past or future conduct. Individual lawsuits arising from past conduct could claim only compensatory damages, whereas individual lawsuits arising from future conduct could claim both compensatory and punitive damages. Defines permissible parties that can act as plaintiffs and defendants is such lawsuits. Limits the total damages paid by the industry in any one year to 33% of the annual industry base payment.[n]
IX. Board Approval	The terms of the settlement are subject to approval by the Boards of Directors of the participating tobacco companies.

[a] The nine warnings on cigarettes packs include: "WARNING: Cigarettes are addictive" and "WARNING: Cigarettes cause cancer." The four warnings on smokeless tobacco products include: "WARNING: Smokeless tobacco is addictive" and "WARNING: This product can cause mouth cancer." The warnings would appear in Canadian format (i.e., alternating black text on a white background and white text on a black background). They would be introduced concurrently on all tobacco product packages and cartons, and rotated

quarterly on all advertisements. The settlement preserves the preemptive language in both the Federal Cigarette Labeling and Advertising Act and the Comprehensive Smokeless Tobacco Health Education Act, which prevents state and local governments from requiring additional health warnings on tobacco products.

[b] Class II medical devices (e.g., syringes, hearing aids, and powered wheelchairs) are those for which FDA requires special controls to assure safety and effectiveness. These controls may include special labeling requirements, mandatory performance standards, and postmarket surveillance.

[c] Most regulations are issued informally under the notice-and-comment procedure established by the Administrative Procedure Act (APA; 5 U.S.C. 551 *et seq.*). The agency publishes a notice of proposed rule making in the Federal Register, permits interested persons to submit comments, and incorporates in the final rule a concise statement of the rule's basis and purpose. These regulations are reviewed under the "arbitrary, capricious, abuse of discretion" standard. Under this standard, a reviewing court would uphold an agency's action if it is rational, based on a consideration of the relevant factors, and within the scope of the authority designated to the agency by Congress. The settlement, however, would require FDA to undertake a formal rule making subject to the APA. This would involve trial-type hearings at which parties present evidence and conduct cross examinations. Furthermore, the "substantial evidence" standard required by the settlement may be more stringent than the "arbitrary, capricious, abuse of discretion" standard employed in informal rule making.

[d] This presumably refers to the Small Business Regulatory Fairness Enforcement Act of 1996 (P.L. 104-121), under which Congress has 60 session days to block a regulation by passing a joint resolution of disapproval. This procedure may be applied to any rule that results in an annual effect on the economy of at least $100 million.

[e] A Part 12 hearing refers to a formal evidentiary public hearing under FDA regulations (21 C.F.R. 12), involving presentation of evidence, cross examination, and other trial-type procedures. Requiring that an agency base its action on a "preponderance of evidence" is, according to some analysts, extremely unusual.

[f] The term "less hazardous tobacco products" refers to innovative products such as smokeless cigarettes, as opposed to chemically modified existing products.

[g] Under current law, the industry is required to provide annually to the Secretary of Health and Human Services a list of all the additives used in the manufacture of tobacco products. The Secretary is granted no authority to regulate additives that are suspected of being hazardous.

[h] The Tobacco Institute is the industry's Washington DC-based lobbying organization, and the Council for Tobacco Research provides industry funds for biomedical research.

[i] The Synar Amendment to the Public Health Services Act requires states to enforce their laws prohibiting the sale of tobacco products to individuals under age 18. States must conduct annual random, unannounced inspections of retail outlets to ensure compliance with the law. States risk losing federal substance abuse block grant funds for failure to comply. Under the settlement, a state would lose up to 20% of its Medicaid reimbursement funds (see Title VI) if after 10 years its enforcement program failed to reach a 90% compliance rate.

[j] On March 25, 1994, the Occupational Safety and Health Organization (OSHA) proposed an indoor air quality regulation that would restrict smoking to separately ventilated, designated smoking rooms. The smoking restriction would apply to all industrial and non-industrial buildings under OSHA's jurisdiction, including restaurants and bars.

[k] The settlement negotiators intend that funding provided to the states would be sufficient to extend health insurance to uninsured children.

[l] It is estimated that the industry could cover the cost of the annual payments by raising the price on a pack of cigarettes by about 62 cents.

[m] This 25-year total includes approximately $60 billion in lieu of punitive damages for tobacco industry's past conduct.

[n] By the fifth year of the settlement, the total amount the industry would be required to pay would be capped at $5 billion per year.

TABLE 2: FDA's REGULATION OF CIGARETTES AND SMOKELESS TOBACCO PRODUCTS		
Section	**Provisions**	**Effective Date**
Labeling (Sec. 801)	Exempts cigarettes and smokeless tobacco from section 502(f)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA), which requires labels on drugs and medical devices to bear adequate directions for use.[a] *21 CFR §801.126*	N/A
Medical Device Reporting (Sec. 803)	Requires manufacturers of cigarettes and smokeless tobacco to submit reports only for serious adverse health events beyond those well-documented by the scientific community, including events related to product contamination, or a change in any ingredient or manufacturing process. *21 CFR §803.19(f)(g)*	August 28, 1997
Medical Device Distributor Reporting (Sec. 804)	Requires distributors of cigarettes and smokeless tobacco to submit reports only for adverse health events related to contamination. *21 CFR §804.25(c)*	August 28, 1997
Registration and Listing of Medical Devices (Sec. 807)	Requires manufacturers of cigarettes and smokeless tobacco to comply with establishment registration and device listing requirements for medical devices. *21 CFR §807.65(j)*	August 28, 1998
Good Manufacturing Practice (GMP) for Medical Devices (Sec. 820)	Requires manufacturers of cigarettes and smokeless tobacco to comply with GMP regulations for medical devices. Distributors of tobacco products are exempted from this requirement. *21 CFR §820.1(e)(f)*	August 28, 1998
Youth Access, Labels, and Advertising (Sec. 897)		
General responsibilities of manufacturers, distributors, and retailers	Manufacturers, distributors, and retailers are responsible for complying with all applicable requirements of this regulation. *21 CFR §897.10*	August 28, 1997
Additional responsibilities of manufacturers	Manufacturers must remove from each point of sale all self-service displays, advertising, labeling, and other items owned by the manufacturers that do not comply with the requirements of this regulation. *21 CFR §897.12*	August 28, 1997
Prohibition of sale and distribution to persons younger than age 18	(i) Retailers may not sell cigarettes or smokeless tobacco to persons younger than age 18. (ii) Persons under age 27 must verify age by means of photographic identification. *21 CFR §897.14(a)(b)*	**Took effect on February 28, 1997**
Additional responsibilities of retailers	(i) Retailers must perform sale in a direct, face-to-face exchange without assistance of mechanical or electronic device (e.g., vending machine). (ii) Retailers may not sell or distribute individual cigarettes. (iii) Retailers must remove all self-service displays, advertising, labeling, and other items that do not comply with this regulation. *21 CFR §897.14(c)(d)(e)*	August 28, 1997

TABLE 2: FDA's REGULATION OF CIGARETTES AND SMOKELESS TOBACCO PRODUCTS

Section	Provisions	Effective Date
Conditions of manufacture, sale, and distribution	(i) Prohibits manufacturers from using a trade name or product name of a non-tobacco product for a cigarette or smokeless tobacco product unless such names were in use prior to 1/1/95. (ii) Prohibits distribution and sale of cigarette packages containing fewer than 20 cigarettes. (iii) Bans vending machines and self-service displays except in locations where the retailer ensures that no person under age 18 is permitted at any time. Permits mail-order sales. (iv) Bans distribution of free samples of cigarettes and smokeless tobacco. (v) Bans sale and distribution of cigarettes and smokeless tobacco with labels, labeling, or advertising not in compliance with this regulation. *21 CFR §897.16(a)(b)(c)(d)(e)*	August 28, 1997
Package labels	Cigarette and smokeless tobacco packages must bear an appropriate, established name (e.g., "Cigarettes" or "Loose Leaf Chewing Tobacco") and include the following statement: "Nicotine-Delivery Device for Persons 18 or Older." *21 CFR §897.24, 21 CFR §897.25*	August 28, 1997
Permissible forms of labeling and advertising[b]	(i) Permits labeling and advertising of cigarettes and smokeless tobacco products in newspapers, magazines, periodicals, billboards, posters, placards, in nonpoint-of-sale promotional materials (including direct mail), and in point-of-sale promotional materials (including audio and video formats). FDA must be notified of any intention to use any other medium not listed. (ii) Bans outdoor advertising of cigarettes and smokeless tobacco within 1000 feet of a public playground, elementary or secondary school. *21 CFR §897.30(a)(b)*	August 28, 1997
Format and content requirements for labeling and advertising	(i) Cigarettes and smokeless tobacco labeling and advertising must use only black text on a white background. Publications read by fewer than 2 million persons under age 18, or whose youth readership is 15 percent or less of the total readership are exempt from this requirement. (ii) Labeling and advertising in an audio format is limited to words with no music or sound effects. Video format is limited to static black text on a white background. (iii) Labeling and advertising must include the product's established name, followed by the words: "A Nicotine-Delivery Device for Persons 18 or Older." *21 CFR §897.32(a)(b)(c)*	August 28, 1997
Sale and distribution of non-tobacco items, services, and gifts	(i) Prohibits marketing, licensing, distribution or sale of all non-tobacco items and services that are identified with a cigarette or smokeless tobacco product brand name or other identifying characteristic (e.g., promotional tee shirts and caps). (ii) Prohibits gifts of non-tobacco items as well as credits and coupons that are linked to the purchase of cigarettes and smokeless tobacco. *21 CFR §897.34(a)(b)*	August 28, 1997
Sponsorship of events	Bans brand-name sponsorship of sporting and other cultural and social events. Only corporate-name sponsorship permitted. *21 CFR §897.34(c)*	August 28, 1998

Source: Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents. *Federal Register*, v. 61, no. 168, Aug. 28, 1996. p. 44396-45318.

[a] The regulation does not exempt tobacco products from section 502(f)(2) of the FFDCA, which requires adequate warnings against use by children and others whose medical condition (e.g., pregnancy) makes use of the product dangerous to health. According to FDA, this requirement is satisfied by the rotating Surgeon General's warning labels. The regulation also requires package labeling for *intended use*. According to FDA, this requirement is satisfied by sections 897.24 and 897.25 of the regulation.

[b] The terms "labeling and advertising" are used in sections 897.30 and 897.32 to include all commercial uses of the brand name of a product, logo, symbol, motto, selling message, or any other indicia of product identification similar or identical to that used for any brand of cigarette or smokeless tobacco product.